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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

GILEAD SCIENCES, INC.,

Plaintiff and Counterdefendant,

v.

MERCK & CO., INC. (Defendant only), MERCK
SHARP & DOHME CORP., and ISIS
PHARMACEUTICALS, INC.

Defendants and Counterclaimants.

Case No. 5:13-cv-04057-BLF

**DEFENDANTS' OPENING CLAIM
CONSTRUCTION BRIEF**

Date: April 3, 2015
Time: 9:00 a.m.
Ct rm: 3, 5th Floor
Judge: Honorable Beth Labson Freeman

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1 **I. INTRODUCTION**

2 Merck & Co., Inc., Merck Sharp & Dohme Corp., and Isis Pharmaceuticals, Inc., (collectively,
3 “Merck”) respectfully submit this brief in support of their proposed constructions of the terms
4 “administering” and “compound” as used in the asserted claims of U.S. Patent Nos. 7,105,499 (“the ’499
5 Patent”) and 8,481,712 (“the ’712 Patent”) (collectively, the “patents-in-suit” or “Merck Patents”).

6 The patents-in-suit share a largely identical specification. Both patents disclose novel chemical
7 compounds that are useful for treating Hepatitis C virus (“HCV”) infection. The claims of the ’499
8 Patent are directed to methods of treating HCV infection by administering specified compounds,
9 identified by their chemical structure. The claims of the ’712 Patent are directed to specified compounds,
10 also identified by their chemical structure. The parties dispute the proper meaning of two claim terms:
11 “*administering*” as used in the ’499 Patent, and “*compound*” as used in both patents-in-suit.

12 Merck’s proposed constructions are grounded in the plain meaning of the claim language, the
13 specifications of the patents-in-suit (i.e., intrinsic evidence), and first principles of claim construction as
14 set forth by the Federal Circuit. For example, Merck’s proposed construction of “administering” is taken
15 *verbatim* from the specification, which expressly defines the meaning of this term. Merck’s proposed
16 construction of “compound” is grounded in the plain and ordinary meaning of the term, the usage of that
17 term in the specifications of the patents-in-suit, and the meaning that other courts have construed the term
18 “compound” to have, as discussed below.

19 In contrast, Gilead Sciences, Inc. (“Gilead”) asks the Court to “construe” the claim terms
20 “administering” and “compound” in a manner that would effectively re-write the claims to include
21 multiple new limitations that have no basis whatsoever in the meaning of those terms, either in general or
22 as used in the specifications of the patents-in-suit. With regard to the claim term “administering,” Gilead
23 asks the Court to negate the patents’ express definition of the term “administering” by adding no fewer
24 than 24 extra words to that definition. With regard to the claim term “compound,” Gilead’s proposed
25 construction departs from the plain and ordinary meaning of this term and conflicts with the way this
26 term is used in the specifications of the patents-in-suit, and as such contravenes first principles of claim
27 construction.
28

Merck's proposed constructions are true to the intrinsic evidence and merely explain the disputed terms in language that will be easier for jurors to understand. For the reasons set forth herein, Merck respectfully request that the Court adopt Merck's proposed construction for each disputed claim term.

II. BACKGROUND AND OVERVIEW OF THE TECHNOLOGY

A. Hepatitis C Virus Infection

Hepatitis C virus (HCV) infection is a viral disease that is transmitted by contaminated blood and blood products, by contaminated needles, sexually, and from infected mothers to their children. Rabinowitz Decl., Ex. 1, '499 Patent at col. 1, lines 42-45. A majority of infected individuals harbor HCV for the rest of their lives, and a significant proportion develop liver-destroying cirrhosis or cancer of the liver. *Id.* at col. 1, lines 38-42.

HCV infection has been a major health care problem for decades. Prior to Merck's invention, treatment for HCV infection was restricted to immunotherapy with recombinant interferon- α alone or in combination with a drug called "ribavirin," which had limited clinical benefit. *Id.* at col. 1, lines 45-48. Accordingly, there was an urgent need for new drugs to combat chronic HCV infection. *Id.* At col. 1, lines 50-51.

B. Merck Opened the Way for Innovative New Therapies for HCV Infection

In order to meet this need, the Merck inventors focused on an enzyme called "NS5B polymerase" that the HCV virus depends on in order to reproduce in infected individuals. *Id.* at col. 2, lines 17-22.. After many years of research and development, scientists at Merck and Isis invented novel chemical compounds that are potent inhibitors of the HCV NS5B polymerase and that are useful for treating individuals suffering from HCV infection. *Id.* at col. 1, lines 18-25.

As used in the field of chemistry, the term "compound" means "a substance that consists of two or more chemical elements in union." Rabinowitz Decl., Ex. 2, Dorland's Illustrated Medical Dictionary (29th ed., 2000) at p. 388 (MERCK0064538). For example, water (H₂O) is a compound formed by the union of two chemical elements: hydrogen (H) and oxygen (O). The '712 Patent is directed to compounds, identified by structural formula, that are useful for treating HCV infection. Rabinowitz Decl., Ex. 3, '712 Patent at cols. 143-146, claims 1-9. The '499 Patent is directed to methods of treating HCV infection by administering specified compounds, identified by structural formula, to an infected

individual. Rabinowitz Decl., Ex. 1, '499 Patent at cols. 137-138, claims 1-2.

When a chemical compound is to be administered for purposes of treatment (i.e., as a drug), a commonly used therapeutic strategy is to provide a derivative of the compound (called a “prodrug”) which, following ingestion, is converted by the patient’s body into the active drug. Rabinowitz Decl., Ex. 4, V.J. Stella et al, Prodrugs. Do They Have Advantages in Clinical Practice?, *Drugs* 29: 455-473 (1985) at MERCK0064542 (explaining that prodrugs are “derivatives of a drug molecule that require a transformation within the body to release the active drug.”). By this means, the properties of drugs can be altered, in a temporary manner, to increase their efficacy or to decrease associated toxicity. (*Id.*) Prodrugs are abundant in the pharmaceutical industry and have been used since the nineteenth century. (*Id.* at MERCK0064543-54.)

The Merck Patents expressly teach that a prodrug strategy can be used to treat HCV infection by “providing . . . a prodrug of a compound of the invention to the individual in need.” '499 Patent at col. 32, lines 5-8; '712 Patent at col. 32, lines 51-54 (emphasis added).

The accused product in this action, Sofosbuvir, is a prodrug marketed by Gilead for the treatment of HCV infection. The therapeutic action of Sofosbuvir depends on its being converted in the body, after absorption, into a series of compounds, including compounds known as “PSI-7411,” “PSI-7410,” and “PSI-7409.” ECF 51, Counterclaims at ¶¶ 14-15; ECF 67, Answer to Counterclaims at ¶ 14 (admitting that “the metabolic pathway for Sofosbuvir in humans may produce, *inter alia*, amounts of compounds designated by Pharmasset as PSI-7411, PSI-7410, and PSI-7409.”). Since these three compounds satisfy the structural formulas set forth in the asserted claims of the patents-in-suit, Merck contends that end users of Sofosbuvir directly infringe the patents-in-suit, ECF 51, Counterclaims at ¶¶ 17, 27, 28, and that Gilead is liable for actively inducing and contributing to direct infringement by end users of its Sofosbuvir product. *Id.* at ¶¶ 21- 23, 30-32.

III. THE LEGAL STANDARD FOR CLAIM CONSTRUCTION

The claims of a patent define its scope, and the construction of claim terms is a question to be decided by the Court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995), *aff’d*, 517 U.S. 370, 391 (1996). Claim construction is simply a way of elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims. *Embrex, Inc. v.*

Serv. Eng'g Corp., 216 F.3d 1343, 1347 (Fed. Cir. 2000). The Federal Circuit has prioritized the various sources that may be considered in interpreting claim terms, giving priority to intrinsic evidence (the patent claims, specification, and prosecution history) over extrinsic evidence (dictionaries, learned treatises, expert testimony). *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316-18 (Fed. Cir. 2005) (en banc).

Claim construction begins with the words of the claim itself, which generally receive their ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of the invention. *Id.* at 1312-13. The context of the surrounding words in the claim must also be considered, as it provides substantial guidance to the meaning of disputed terms. *Id.* at 1314. In construing a claim term, a court must look at the term's ordinary meaning in the context of the written description and the prosecution history. *Id.* at 1313.

A. Intrinsic Evidence

Intrinsic evidence must be considered first as such evidence is “the most significant source of the legally operative meaning of disputed claim language.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). All intrinsic evidence, however, is not equal. *See id.* (delineating a hierarchy among the intrinsic evidence). Where “the claim language is clear on its face, then our consideration of the rest of the intrinsic evidence is restricted to determining if a deviation from the clear language of the claims is specified.” *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001). “If however the claim language is not clear on its face, then our consideration of the rest of the intrinsic evidence is directed to resolving, if possible, the lack of clarity.” *Id.*

Claims do “not stand alone” rather they “are part of a fully integrated written instrument,” and thus must be read in view of the specification. *Phillips*, 415 F.3d at 1315. To that end, “the specification is always highly relevant to the claim construction analysis.” *Id.* (citation and internal quotation marks omitted). “Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Id.*; *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002) (“[A] claim term will not receive its ordinary meaning if the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term in either the specification or prosecution history.”).

The examples set forth in the specification, however, cannot be used to read limitations into claims. *See, e.g., Phillips*, 415 F.3d at 1323; *Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1327 (Fed. Cir.

2012) (“As a general rule, it is improper to read limitations from a preferred embodiment described in the specification”) (citation and internal quotation marks omitted); *3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1372 (Fed. Cir. 2003) (“Limitations from the specification, however, cannot be imported into the claims, and this rule must be strictly enforced”). Indeed, “although the specification often describes very specific embodiments of the invention,” the Federal Circuit has “repeatedly warned against confining the claims to those embodiments.” *Phillips*, 415 F.3d at 1323. Further, a “patentee need not describe in the specification every conceivable and possible future embodiment of his invention.” *CCS Fitness*, 288 F.3d at 1366 (citation and internal quotation marks omitted).

The court may also consider the prosecution history. *Sorensen v. Int’l Trade Comm’n*, 427 F.3d 1375, 1378 (Fed. Cir. 2005). Notably, any disclaimer of claim scope in the prosecution history must be “both clear and unmistakable.” *Id.* at 1378-79. Intrinsic evidence alone will resolve any ambiguity in most situations. *Vitronics*, 90 F.3d at 1583.

B. Extrinsic Evidence

If the meaning of the claim language is still ambiguous notwithstanding the intrinsic evidence, the court may consider extrinsic evidence, “in order to aid the court in coming to a correct conclusion as to the true meaning of the language employed in the patent.” *Markman*, 53 F.3d at 980 (citations and internal quotation marks omitted). While extrinsic evidence can be useful, “it is less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Phillips*, 415 F.3d at 1317.

Dictionaries and technical treatises are preferred sources of extrinsic evidence because they can provide accepted meanings of terms not biased by litigation. *Id.* at 1318; *see also Vitronics*, 90 F.3d at 1584 n.6. Nonetheless, “heavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification.” *Phillips*, 413 F.3d at 1321.

As the Federal Circuit explained, “the construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Id.* at 1316 (citations and internal quotation marks omitted).

IV. THE PROPER CONSTRUCTION OF DISPUTED CLAIM TERMS

A. “Administering”

Claim Term	Merck’s Proposed Construction	Gilead’s Proposed Construction
“administering” (Claim 1, ’499 Patent)	providing a compound of the invention or a prodrug of a compound of the invention to the individual in need.	providing a compound of the invention or a prodrug of a compound of the invention to the individual in need <i>without reference to in vivo transformations of those compounds or prodrugs.</i> <i>The phrase “prodrug of a compound” means those prodrugs that are expressly claimed.</i>

1. Merck’s Construction Is Consistent With the Specification and Is Proper Under the Accepted Principles of Claim Construction

The term “administering” should be construed to mean “providing a compound of the invention or a prodrug of a compound of the invention to the individual in need,” the definition expressly set forth in the specification. Gilead’s proposed construction contains crucial flaws and contravenes well-established rules of claim construction.

Acting as their own lexicographer, the patentees assigned a meaning to the term “administering:”

The terms “administration of” and “administering a” compound should be understood to mean *providing a compound of the invention or a prodrug of a compound of the invention to the individual in need.*

Rabinowitz Decl., Ex. 1, ’499 Patent at col. 32, lines 5-8 (emphasis added). Where, as here, the specification provides an explicit definition for a claim term, courts adopt a construction consistent with the meaning set forth in the specification. *See, e.g., 3M Innovative*, 350 F.3d at 1374 (“Because [the patentee] expressly acted as its own lexicographer by providing a definition of [the disputed claim term] in the specification, the definition in the specification controls . . . regardless of any potential conflict with the term’s ordinary meaning as reflected in technical dictionaries.”); *CCS Fitness*, 288 F.3d at 1366; *Vitronics*, 90 F.3d at 1585 (“Because the specification clearly and unambiguously defined the disputed term in the claim, reliance on this extrinsic evidence was unnecessary and, hence, legally incorrect.”). Accordingly, the Court should adopt Merck’s construction of the term “administering.”

2. **Gilead’s Construction Imports Limitations That Are Absent from the Claim Language and Are Inconsistent with the Specification.**

As discussed below, Gilead’s proposed construction of “administering” should be rejected because it improperly asks the Court to re-write the claim to include extraneous limitations having nothing to do with the proper meaning of the word “administering.” Gilead does not dispute that the definition of “administering a” set out in column 32, lines 5-8 of the specification is consistent with and supports Merck’s proposed construction of “administering.” Gilead itself invokes this definition but asks the Court to modify the specification definition of “administering” by appending two wholly extraneous limitations having nothing to do with the proper meaning of “administering.” The two proposed additional limitations are:

- (a) *“without reference to in vivo transformation of those compounds or prodrugs;”* and
- (b) *“the phrase ‘prodrug of a compound’ means those prodrugs that are expressly claimed.”*

The above-quoted language is both extraneous to the meaning of “administering” and inconsistent with the specification and, thus, should be rejected. *See, e.g., Merck & Co. v. Teva Pharms. USA, Inc.*, 347 F.3d 1367, 1371 (Fed. Cir. 2003) (“[C]laims must be construed so as to be consistent with the specification, of which they are a part.”).

a. “without reference to in vivo transformation of those compounds or prodrugs”

In determining the proper construction of a claim term, the context of the surrounding words of the claim is important. *See, e.g., ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003) (“[T]he context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning of those terms.”); *IGT v. Bally Gaming Int’l, Inc.*, 659 F.3d 1109, 1117 (Fed. Cir. 2011) (“We caution that claim language must be construed in the context of the claim in which it appears.”); *Phillips*, 415 F.3d at 1314. Here, the text of claim 1 of the ’499 Patent clearly does not support Gilead’s proposed construction.

Claim 1 of the ’499 Patent recites, in relevant part:

A method of treating hepatitis C virus (HCV) infection comprising
administering to a mammal in need of such treatment a therapeutically

effective amount of *a compound of structural formula III* or a pharmaceutically acceptable salt or acyl derivatives thereof

Rabinowitz Decl., Ex. 1, '499 Patent at col. 137 (emphasis added). The above-quoted language merely requires “administering” a compound that satisfies the structural formula set forth in the claim. And the term “administering” is specifically defined in the specification so as to include providing compounds that are formed in the body by in vivo transformation of a prodrug. As the specification expressly states

The terms “administration of” and “administering a” compound should be understood to mean providing a compound of the invention *or a prodrug of a compound of the invention* to the individual in need.

Id. at col. 32, lines 5-8 (emphasis added). Thus, the specification explicitly defines the term “administering . . . a compound” to include providing a prodrug that is converted in the body to a compound of the invention. This definition requires that the infringement analysis take account of in vivo transformation of a prodrug after ingestion by the patient – exactly the opposite of what Gilead proposes in its claim construction. Gilead’s construction seeks to narrow the claim by limiting the term “compound” to ingested compounds only by specifying that the claim excludes compounds arising from *in vivo* transformation (also known as “metabolism”). *But cf. Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1375 (Fed. Cir. 2003) (“A metabolite is the *compound* formed in the patient’s body upon ingestion of a pharmaceutical. The ingested pharmaceutical undergoes a chemical conversion in the digestion process to form a new metabolite *compound*.”) (emphasis added).

Where, as here, the plain meaning of the claim language is clear and there is no express or implied pre-ingestion limitation, such a limitation is not to be prescribed by judicial “construction.” *See, e.g., Zenith Labs., Inc. v. Bristol-Myers Squibb Co.*, 19 F. 3d 1418, 1421-22 (Fed. Cir. 1994) (finding that a compound claim covers compounds formed in a patient’s body after ingestion) (“[W]hile the claim as issued is limited to [a specified] crystalline form . . . it is not limited to the compound in its pre-ingested form”); *Schering*, 339 F.3d at 1381 (claims directed towards compounds “broadly encompass compounds defined by structure only.” “Such bare compound claims include within their scope the recited compounds as chemical species in any surroundings, *including within the human body as metabolites of a drug*.”) (emphasis added); *Merck*, 47 F.3d at 1371 (holding that a claim “directed to method of treatment” by “administering an effective amount of the specified biphosphonic acid,” was not

1 limited to pre-ingested form where “the acid is the active agent and . . . the acid is administered when it is
 2 in the form of the [pre-ingested] salt.”); *Ortho-McNeil Pharma., Inc. v. Mylan Labs., Inc.*, 348 F. Supp.
 3 2d 713, 730 (N.D.W.Va. 2004) (rejecting construction that excludes *in vivo* production of the claimed
 4 compound: “[w]hether levofloxacin formed as the claimed compound inside the body or outside the
 5 body, as long as it is given remedially as medicine, then levofloxacin has been administered.”).

6 Gilead’s proposed construction of “administering” is a transparent attempt to have the Court
 7 “construe” the word “administering” so as to exclude from its scope the use of prodrugs, such as
 8 Sofosbuvir, as a means of administering the compounds recited in the claim. It was precisely to address
 9 this type of delivery mechanism, and to include compounds formed *in vivo* by metabolism, that the
 10 specification of the ‘499 Patent includes the express definition of “administering” that it does. The Court
 11 should decline Gilead’s invitation to re-write the claim so as to exclude from its scope what the claim
 12 actually describes. *Cf. Phillips*, 415 F.3d at 1316 (“[T]he specification may reveal a special definition
 13 given to a claim term by the patentee In such cases, the inventor’s lexicography governs.”).

14 Accordingly, the court should adopt Merck’s construction of the term “administering.”

15 **b. “The phrase ‘prodrug of a compound’ means those prodrugs that are**
 16 **expressly claimed”**

17 This aspect of Gilead’s proposed construction of “administering” is likewise inconsistent with the
 18 claim’s plain language and first principles of claim construction. In the context of “administering,” use
 19 of a prodrug is simply one way that novel compounds of the invention can be provided to a patient. A
 20 “prodrug” in this context is merely a delivery vehicle. The method described by claim 1 of the ‘499
 21 Patent is simply not restricted to particular delivery vehicles for providing the compounds described in
 22 the claim. The above-quoted language has nothing to do with the meaning of “administering” but is,
 23 once again, a transparent attempt to have the Court “construe” that term in a manner that contradicts the
 24 specification and defines “administering” by reference to an extraneous limitation that has nothing to do
 25 with “administering,” namely, “prodrugs that are expressly claimed.” Claim 1 of the ‘499 Patent does
 26 not use the term “prodrugs” and there is simply no basis for the Court to append to the claim the
 27 additional limitation that Gilead proposes. As noted above, the specification defines “administering” to
 28 include providing “a prodrug of a compound of the invention,” i.e., a prodrug that converts in the body to

a compound that is expressly claimed. *See* discussion III.A.2.a *supra*. Gilead’s proposed construction of “prodrug” is inconsistent with the specification.

Accordingly, the Court should reject Gilead’s attempt to limit the scope of “administering” by adding extraneous and restrictive words.

B. “Compound”

Claim Term	Merck’s Proposed Construction	Gilead’s Proposed Construction
compound (claims 1-2, ’499 Patent; claims 1-3, 5, 7, and 9-11, ’712 Patent)	A substance that consists of two or more chemical elements in union.	The term “compound” refers to synthetically produced compounds only.

The term “compound” should be construed to mean “a substance that consists of two or more chemical elements in union.” Merck’s construction is consistent with the way the term “compound” is used in the specification of the patents-in-suit, and accords with the plain and ordinary meaning of this term as understood by a person of ordinary skill in the art. In contrast, Gilead’s proposed construction adds an extraneous limitation “synthetically produced . . . only” that is at odds both with the way this term is used in the specification and with its ordinary technical meaning.

Merck’s construction accords with the way the term “compound” is used in the largely identical specifications of the patents-in-suit, which explain that the invention may be practiced by providing “a compound of the invention *or a prodrug of a compound of the invention* to the individual in need.” Rabinowitz Decl., Ex. 1, ’499 Patent at col. 32, lines 5-8; *id.*, Ex. 3, ’712 Patent at col. 32, lines 51-54. (emphasis added). Thus, the specification uses the term compound to describe: (i) a compound that is synthetically produced and then given to a patient, as well as (ii) a compound that is produced in the body by metabolism of a prodrug that is given to a patient. *See Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 991 (Fed. Cir. 1999) (“Varied use of a disputed term in the written description demonstrates the breadth of the term rather than providing a limited definition.”). This broad, inclusive use of the term “compound” accords perfectly with Merck’s construction but not with Gilead’s proposal, which would artificially limit “compound” to mean a “synthetically produced compound only” so as to exclude a compound that results from metabolism of a prodrug.

Merck's construction also accords with way chemists normally use the term "compound." As the Federal Circuit has explained, the Court may consider extrinsic evidence, "to aid the court in the construction of the patent." *Markman*, 53 F.3d at 980 (citation omitted). Dictionaries are "among the many tools that can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention." *Phillips*, 415 F.3d at 1318.

Contemporaneous technical dictionaries define "compound," as used in the field of medicine and chemistry, to mean "a substance that consists of two or more chemical elements in union." *See, e.g.*, Rabinowitz Decl., Ex. 2, Dorland's Illustrated Medical Dictionary (29th ed., 2000), at p. 388 (MERCK0064538); Rabinowitz Decl., Ex. 5, Stedman's Medical Dictionary (27th ed., 2000), at p. 392 (MERCK0064541); Rabinowitz Decl., Ex. 6, Mosby's Medical, Nursing & Allied Health Dictionary (6th ed., 2002), at p. 406 (MERCK0064535.)

Merck's construction is also consistent with the way district courts have construed the term "compound" as used in comparable patents. *See, e.g., Aventis Pharma Deutschland GmbH v. Lupin Ltd.*, No. 2:05CV421, 2006 WL 1314413, at *4 (E.D. Va. May 11, 2006) (holding that "'a compound' is a fairly broad term meaning a chemically distinct substance formed by *union of two or more ingredients (as elements)* in definite proportion by weight and definite structural arrangement.") (emphasis added) (citation and internal quotation marks omitted); *Ortho-McNeil*, 348 F. Supp. 2d at 728 (finding that "'compound' means 'a chemically distinct *substance formed by union of two or more ingredients (as elements)* in definite proportion by weight and with definite structural arrangement <water is a [compound] of oxygen and hydrogen>.'"') (emphasis added) (citing Webster's Third New Int'l Dictionary 466 (2002)).

The Federal Circuit has made clear that "a court must presume that the terms in a claim mean what they say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning of claim terms." *Johnson*, 175 F.3d at 989. Accordingly, the Court should adopt Merck's proposed construction of the term "compound."

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V. CONCLUSION

For the reasons discussed above, Merck respectfully requests that the Court adopt its proposed constructions.

Dated: October 27, 2014

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CERTIFICATE OF SERVICE

I certify that all counsel of record are being served on October 27, 2014 with a copy of this document via the Court's CM/ECF system.

/s/ Stephen S. Rabinowitz
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